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Dated: June 17, 2003 Signature: Susan Hunter (Susan Hunter)

#91 SD 6/23/03

Docket No.: HO-P02086US1 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
James R. Lupski, et al

Application No.: 10/021,955

Filed: December 13, 2001

Group Art Unit: 1637

Examiner: S. Chunduru

(10026309)

For: DEFECTS IN PERIAXIN ASSOCIATED WITH MYELINOPATHIES

RESPONSE TO RESTRICTION REQUIREMENT AND PRELIMINARY AMENDMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action mailed February 19, 2003. A Petition for Extension of Time of Three Months and the requisite fee are filed herewith.

The Examiner has required restriction between the following:

Group I (Claims 1-13), drawn to a method of diagnosing myelinopathy in an individual based on an alteration in a periaxin polynucleotide, requiring SEQ ID NOS:1-77;

Group II (Claims 14, 32-34), drawn to a composition of matter and a kit comprising a polynucleotide, requiring SEQ ID NOS:3-26;

Group III (Claims 15-16), drawn to a composition of matter comprising a polypeptide;

Group IV (Claims 17-20), drawn to a method of identifying or screening a compound agent for treating a myelinopathy;

Group V (Claims 21-23), drawn to a method of identifying an upregulator or a drug activity;

Group VI (Claims 24-26), drawn to a method of treating an organism comprising a therapeutically effective amount of a nucleic acid sequence;

Group VII (Claims 27-28), drawn to a method of treating an organism comprising a therapeutically effective amount of an amino acid sequence;

Group VIII (Claims 29-31), drawn to a method of treating an organism comprising a therapeutically effective amount of a compound; and

Group IX (Claims 35-40), drawn to a method of detecting the presence or absence of a mutation associated with a myelinopathy, requiring SEQ ID NOS:1-77.

Applicants, represented by Melissa L. Sistrunk, telephoned Examiner Chunduru on March 27, 2003 regarding grouping of the claims. Applicants notified the Examiner that Group I drawn to Claims 1-13 erroneously grouped claims directed to polypeptide sequences, and suggested Group I should include only Claims 1-7. The Examiner agreed.

Applicants also discussed with the Examiner the nature of restriction between Group I and Group IX, and the Examiner suggested addressing the issue in the response.

Applicants traverse the restriction between Group I and Group IX. The claims in Group I are directed to a method of diagnosing myelinopathy in an individual by obtaining a sample containing nucleic acid from the individual; and assaying the sample for an alteration in a periaxin polynucleotide, wherein the alteration is associated with the myelinopathy. Group IX is directed to a method of detecting the presence or absence of a mutation associated with a myelinopathy by isolating a test periaxin nucleic acid from a subject, comparing the test nucleic acid to a reference wild-type periaxin polynucleotide; and determining the differences between the test nucleic acid and the reference wild-type periaxin polynucleotide, wherein the differences are mutations in the periaxin polynucleotide of the subject, and wherein the presence of a mutation in the periaxin polynucleotide of the subject is associated with the myelinopathy in the subject.

Applicants respectfully assert that the two groups regard the same invention, with substantially similar steps. Both independent claims, and therefore corresponding Groups, regard obtaining a periaxin polynucleotide and determining whether or not a mutation is present in the periaxin polynucleotide, wherein a mutation in the periaxin polynucleotide is associated with a myelinopathy. Applicants suggest that there would be no undue burden to employ searches for both Groups, as both Groups are so similar in nature. Therefore, Applicants respectfully request consolidation of Group I (the correct one, with only the polynucleotide sequences) and Group IX.

If the Examiner agrees, then Applicants select new Group I/Group IX and elect as a species 247ΔC. If the Examiner does not agree, then Applicants select Group IX and elect as a species 247ΔC. Upon the request of the Examiner, Applicants also select the species SEQ ID NO:76 as the specific nucleotide sequence for examination purposes only.

Applicant reserves the right to pursue non-elected claims in future prosecution and will cancel any remaining non-elected claims upon resolving this grouping issue.

06-18-03

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PTO/SB/21 (05-03)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/021,955
Filing Date	December 13, 2001
First Named Inventor	James R. Lupski
Art Unit	1637
Examiner Name	S. Chunduru
Total Number of Pages in This Submission	
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ENCLOSURES (*check all that apply*)

- [x] Fee Transmittal Form
  - [x] Fee Attached - $465
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):

  Response to Restriction Requirement;
  Return Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	FULBRIGHT & JAWORSKI L.L.P. Melissa L. Sistrunk
Signature	Melissa Sist
Date	June 17, 2003

Transmittal

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